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Overview of Research Addressing Ethical Dimensions of Participation in Traumatic Stress Studies: Autonomy and Beneficence

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One element of the design of human research studies is ethically informed decision-making. Key issues include the safety, costs, and benefits of participation. Historically, much of this decision-making was based on opinion rather than formal evidence. Recently, however, investigators in the traumatic stress field have begun to collect data that are relevant to these decisions. In this article, the authors focus on issues emanating from the ethical concepts of autonomy and respect for persons and beneficence and nonmaleficence, and then summarize relevant evidence from studies with trauma-exposed individuals. Discussion addresses implications of this evidence for research practice and policy, and identifies some potentially informative data collections opportunities for future trauma studies.

Key ethical concerns in the design of human research are to promote safety, minimize costs relative to benefits, and accurately convey information about these considerations to participants. Ethical considerations may have meaningful impact on data quality and validity of results by affecting the way individuals engage with the study procedures. Further, positive experience may increase willingness to volunteer again in the future and promote word-of-mouth encouragement to other potential volunteers. Investigators who study trauma-exposed individuals have led the effort to examine ethically relevant measures and provide evidence that can inform research design decisions. An update on this topic is warranted because evidence has continued to accrue since previous reviews were published (Newman & Kaloupek, 2004; Newman, Risch, & Kassam-Adams, 2006).

This study is organized around two sets of ethical principles: (a) autonomy and respect for persons, and (b) beneficence and nonmaleficence (National Commission for the Protection of Human Subjects of Behavioral Research [National Commission], 1979). Autonomy involves due recognition of both the independence and capabilities of individuals. It recognizes the need for protection of individuals with diminished autonomy, while making full allowance for individuals to enact their own decisions and choices. Beneficence aims to maximize potential benefits of research. This consideration is used to weigh the reasonableness of costs (e.g., inconvenience; discomfort) and potential risks to the individual, whereas the companion principle of nonmaleficence aims to minimize potential for harm and injury.

This overview emphasizes issues of greatest relevance for trauma-related research, including topics about which there is little available evidence. Issues that are unique to research involving trauma-exposed children are not reviewed (see Newman et al., 2006, for information). Subsections examine trauma exposure and posttraumatic stress disorder (PTSD) status as potential moderating characteristics. Coverage includes practical suggestions, methods for evaluating ethical concerns within protocols, and avenues for future study.

The absence of uniform index terms across articles and databases poses a challenge for efforts to review studies that address ethical issues in trauma-focused research. We managed this challenge by using a variety of search terms (e.g., participant reaction, experimental ethics, trauma, abuse, research ethics) across multiple databases (Academic Search Complete; MedLine; PILOTS; PsycInfo), supplemented by an iterative process of examining reference lists of identified articles.

AUTONOMY AND RESPECT FOR PERSONS IN TRAUMA-RELATED RESEARCH

A recurring aim in the traumatic stress field is to understand whether—or under what conditions—individuals who have been

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exposed to trauma or developed PTSD might require special precautions when enrolled in a research protocol. Such precautions may result in changes to recruitment procedures, informed consent, or aspects of the protocol itself. Whereas additional protections are required for any potential research subject who is deemed "vulnerable," vulnerability itself is not defined in federal regulations. Instead, examples of specific protections are identified for four groups that are designated as universally vulnerable: children, prisoners, pregnant women, and embryos (National Commission, 1979). Adults with mental disability, members of ethnically or economically disadvantaged groups, members of marginalized groups, and individuals with incurable diseases are other classes of individuals discussed in terms of vulnerability.

Although it is vital to protect those with diminished capacity, the Belmont Report emphasizes that protection must be accomplished in a respectful manner, "To show lack of respect for an autonomous agent is to repudiate that person's considered judgments" (National Commission, 1979, p. 4). Given the inherent tension between autonomy and protection from harm, an emerging view is that vulnerability in research should be examined in terms of individual characteristics and not based on group membership. Categorization based on group membership rather than consideration of individual strengths and weaknesses makes vulnerability an imprecise construct, which may inadvertently result in stereotyping individuals rather than affording protection from harm (Levine et al., 2004). In fact, vulnerability is probably best conceptualized as falling along a continuum and varying over time and situations (e.g., Levine et al., 2004). Examining possible gradients of and change in vulnerability is a potentially informative target for future research that can inform research practice.

Informed Consent and Decision-Making Capacity

The major focus related to autonomy is an individual's capacity to consent to research. Decisional capacity typically refers to the ability to understand factual information, appreciate the implications of information about the study, manipulate that information, and communicate choice (e.g., Rosenstein, 2004). Most experts agree that, in the absence of impairments such as serious brain injury or acute psychosis, even severely trauma-exposed adults can competently consent to research. Although evidence is limited, the expressed consensus is that decisional capacity is not impaired by virtue of exposure to trauma per se (National Center for Ethics in Health Care, 2008; Rosenstein, 2004).

It is helpful to examine empirical evidence about the circumstances and frequency of trauma-exposed individuals being excluded from studies on the basis of decisional capacity (Collogan, Tuma, Dolan-Sewell, Borja, & Fleischman, 2004; Rosenstein, 2004), but it is rare for published studies to report this information. Among the few studies that have reported about such exclusions is the World Trade Center Evacuation Study in which 3 individuals out of 100 were excluded from interviews or focus group due to the study psychiatrist's concerns about their decisional capacity (Qureshi et al., 2007).

Researchers often cannot examine detailed characteristics such as lifetime history of trauma exposure in relation to decisional capacity exclusions because this information is typically obtained only after study consent. An exception is the longitudinal study of 1,575 children (Widom, 1989) who originally were either exposed to abuse or neglect ($n = 908$) or served as matched nonabused controls ($n = 667$). All of these participants were sought for recontact 20 years later (Widom & Czaja, 2005). The 1,307 participants located 20 years later were relatively representative of the original sample and only 8 (0.6%) were judged to be incapable of being interviewed. Then, of the 1,117 participants located for the third wave of data collection (comprised of 626 with documented abuse or neglect and 491 controls), only 4 (0.36%) were judged unable to be interviewed. Although the authors do not report how many of the exclusions were in the trauma-exposed group, even the worst case amounts to 0.64% and would indicate a relative absence of decisional capacity problems.

The base rate for decisional capacity exclusions in trauma-related studies may be higher among hospitalized psychiatric inpatients. Of 1,013 patients identified for potential study enrollment by Carlson and colleagues (2003), therapists denied the research team permission to approach 13% due to broadly stated impairment in mental capacity or medical incapacity. Although the study did not report proportions based on exclusion type, the mental health nature of the facility suggests that the former may have been the more likely basis for exclusion.

There does not appear to be direct evidence addressing whether PTSD status is a marker for impaired decisional capacity, and the relatively subtle cognitive and memory effects associated with PTSD do not appear potent enough to have substantial impact on this capacity (e.g., Leskin & White, 2007). Similarly, Friedman (2008), noting the relatively intact decision-making capacity for research consent shown by hospitalized schizophrenics, comments that it is unlikely PTSD will be found to affect decision-making capacity to a greater degree.

The overall base rate for impaired decisional capacities is probably low, especially outside psychiatric residential facilities, but even low rates justify case-by-case determination. Routinely noting this type of information in research reports would provide a basis for addressing questions and comparing rates of exclusion for impaired decisional capacity across types of studies and topics.

Coercion and Autonomy

The process of informed consent is predicated on the belief that participants can accurately determine whether it is in their best interests (e.g., in terms of safety) to participate in a particular study and act accordingly. Coercive influences potentially undermine the process. Some have raised concerns that individuals who have experienced interpersonal violence may be unduly influenced

by requests for research participation. In particular, Castor-Lewis (1988) argued that potential power inequities between investigators and participants may manifest themselves similar to those between abusers and the abused, which could, in turn, render decisions by potential research participants less autonomous.

The evidence accrued during the intervening 20 years does not appear to support this contention. Indirect evidence can be gleaned by examining refusal rates for trauma-related studies in general, without knowing individual trauma exposure status. For example, a study of 273 mothers selected on the basis of having delivered a stillborn baby found that 28% declined participation, with half this subgroup citing their preference to not revisit the painful memories (Brabin & Berah, 1995). This indicates that a substantial subgroup of eligible mothers was able to make a choice that ran counter to the experimenter's request. Similarly, among incarcerated women interviewed about victimization experiences, 17% skipped sections or terminated the interview, with a third of these refusals attributable to emotional distress (Hlvaka, Kruttschnitt, & Carbone-Lopez, 2007). Thus, evidence based on two different samples and research procedures indicates that many individuals do exercise autonomy by declining or stopping participation, or by not answering selected questions. This evidence does not preclude the possibility that some individuals experience the situations as coercive, but it shows that broad categorizations (cf. "vulnerable populations") probably do not apply.

The trend suggested by these studies is consistent with evidence that, when asked, most adult and child participants in trauma-focused studies endorse statements indicating that they feel able to refuse participation, to stop or skip questions, and to tell research staff when they do not like aspects of the research protocol (Kassam-Adams & Newman, 2005; Ruzek & Zatzick, 2000). Nonetheless, 19% of participants in one study did endorse feeling unable to refuse participation initially (Ruzek & Zatzick, 2000), which highlights the importance of communicating the voluntary nature of research participation in writing, verbally, and nonverbally during the consent process. It may even be good practice to periodically ask participants whether they wish to continue at points during a protocol rather than requiring them to raise the topic. The impact of this approach might then be evaluated in terms of withdrawal rates and postparticipation ratings about perceived ability to withdraw.

A broadly related concern has been raised with respect to military personnel who are recruited for research: Are members of these groups subject to social, cultural, or command pressures for research participation that can supersede personal preferences? Although a sense of kinship with potential beneficiaries of research findings (e.g., other soldiers) is recognized as an acceptable motive for research participation, the concern is that such motivations can have coercive influence. In addition, the command-based structure of the military may conflict with the formal voluntary nature of research participation. Studies that address the role of perceived kinship and the potential influence of military command in motivating research participation would be a welcome addition to determine whether there is need for concern.

Another ethical issue that arises for trauma-related research is the challenge of adequately imparting the understanding that participation in a clinical study serves to answer a scientific question, in contrast to clinical services that are aimed exclusively at meeting personal needs. Although this issue arises for most treatment-oriented research (Lidz, Appelbaum, Grisso, & Renaud, 2004), it may have particular salience when trauma-exposed individuals are involved. Researchers might implement informed consent procedures that emphasize the research question rather than direct personal benefit (e.g., Collogan et al., 2004). And they may use quiz-type questions as part of the informed consent process to allow study personnel to address misconceptions or misunderstandings before participation occurs. This approach also serves as a source of evidence about the prevalence of such communication issues. Finally, some trauma researchers have encouraged potential participants to consult with family members as a way to promote reflection (e.g., Collogan et al., 2004).

Evidence about PTSD as a risk factor for susceptibility to coercion is difficult to interpret. For example, Matthieu and Ivanoff (2006) found that individuals with more severe PTSD symptoms initially were more likely to withdraw from their treatment study. This may indicate PTSD does not impede one's ability to act, or it may suggest that individuals with more severe PTSD were influenced to participate in an experience that was ill-suited to them. Another treatment study found that participants with greater PTSD symptoms rated their ability to stop participation lower prior to the trial, although this symptom-related difference was not found during the trial itself (Weitlauf, Ruzek, Westrup, Lee, & Keller, 2007). Randomized control trials that include queries about perceived coerciveness could help clarify this important question. Outside of treatment trials, perceived coerciveness is not rated high overall nor related to regret about having participated, although Ruzek and Zatzick (2000) found that the 19% of accident survivors who endorsed the item, "I felt I couldn't say 'no' to participating" had higher PTSD symptom levels that those who did not endorse that particular item.

Considerations for Informed Consent

Participants must fully understand the risks and benefits for true informed consent to occur. In fact, a study need not be risk free if effective informed consent is in place and the scientific value is clear (Kilpatrick, 2004). The adequacy of consent in trauma-related studies has been examined using face-valid measures that assess satisfaction with information imparted by the informed-consent process. Self-report responses to these questions indicate relatively high levels of satisfaction for both children and adults in trauma-related studies (Chu, DePrince, & Weinzierl, 2008; DePrince & Chu, 2008; Kassam-Adams & Newman, 2005; Newman, Willard, Sinclair, & Kaloupek, 2001; Ruzek & Zatzick,

2000). No published findings have specifically examined trauma-related distress with respect to impact on understanding of the consent process with respect to PTSD status.

A final consideration related to autonomy is the level of detail included in informed-consent documents. Investigators and institutional review boards vary in the degree to which informed consent processes explicitly caution participants about the possibility of distress or unexpected harm in trauma-focused research. On one hand, noting cautions may help potential participants weigh the personal costs and benefits of the experience, encourage trust, and provide information that helps participants anticipate and manage emotional reactions during the research protocol. Alternatively, explicit cautions may promote undue anxiety or expectations for an unpleasant emotional experience and inadvertently reduce beneficence (Becker-Blease & Freyd, 2006). Despite its fundamental importance, the issue has not been the target of systematic study and consent practices continue to vary.

BENEFICENCE AND NONMALEFICENCE

The principles of beneficence and nonmaleficence obligate researchers to both maximize possible benefits and minimize possible risks, and to not harm participants. Trauma researchers typically have focused on the potential for distress due to research participation; however, it is important to distinguish transient discomfort (i.e., cost) from lasting psychological or physical harm (i.e., risk). Unexpected distress can be considered as either a cost or a risk depending on the intensity and the degree to which it has potential to produce long-lasting functional impairment.

Minimal risk is defined formally as, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (U.S. Department of Health and Human Services, 2005, 45 CFR 46.102i). It is often unknown how the degree of emotional upset experienced during a research protocol compares to the magnitude of distress participants confront during their daily lives. Further, it is unknown whether any upset reflects acute intensification of existing symptoms or emotional responses that are uncharacteristic of the individuals (Newman & Kaloupek, 2004).

One major advancement has been the use of structured post-participation questioning to obtain information that is directly relevant to minimal risk categorization. Two studies have asked research participants whether the study task was more or less distressing than other things encountered in day to day life (Cromer, Freyd, Binder, DePrince, & Becker-Blease, 2006; DePrince & Freyd, 2004), and both provide evidence consistent with the minimal risk classification.

Emotional responses elicited from research participation may generally fall within the boundaries of minimal risk because direct questions such as those used in research protocols do not tend to elicit painful memories in the same way that everyday exposure (e.g., from media reports) elicits such memories (Becker-Blease & Freyd, 2006). And, if the level of emotional distress during participation is both manageable and typical for the individual, it may reflect emotional engagement in the research project rather than being an indicator of harm (Newman & Kaloupek, 2004). Indeed, Edwards, Kearns, Calhoun, and Gidycz (2009) found that negative emotional reactions experienced during their protocol were associated with perceived personal benefits from participation.

Several researchers have collected qualitative information about the sources and types of distress that research participants experience. Disch (2001) noted several types of research-related reactions reported by participants that included bringing forth painful feelings related to trauma and nontrauma experiences, interfering with daily routine, confronting painful realities, and symptomatic distress. In a study of adult psychiatric inpatients (Carlson et al., 2003), coders organized responses into six categories: remembering/reliving the past, the detailed nature of the questions, painful insights, negative emotions, dissociation, and embarrassment. Thus, distress within the research context seems to be multifaceted.

Typically, researchers have administered face valid questions about upset at the conclusion of an interview, often using items from a version of the Reactions to Research Participation Questionnaire (RRPQ; Newman et al., 2001; Kassam-Adams & Newman, 2002). Samples have included both children and adults exposed to a range of different events including interpersonal violence, disasters, acute injury, military trauma, and war. Whereas the clear majority of participants in these studies do not endorse *unexpected* distress, a noteworthy minority does. Similarly, most distress is rated moderate or lower by participants (e.g., Griffin, Resick, Waldrop, & Mechanic, 2003), but a small subgroup of participants reports distress that seems to have potential to interfere with functioning. For instance, 6.5% of psychiatric inpatients stopped a research interview due to experiencing emotional distress (Carlson et al., 2003), although fewer than 1% of veterans reported a need for increased counseling or medication after completing a survey about PTSD (Halek, Murdoch, & Fiortierl, 2005).

With respect to surveys in particular, evidence suggests that participants who report distress during study procedures do not remain upset at completion (e.g., Boscarino et al., 2004; Galea et al., 2005). This is consistent with the formal definition of minimal risk (U.S. Department of Health and Human Services, 2005). Few studies have examined the long-term effects of research participation, including possible changes in participants' emotional reactions over time after the research experience. One exception is a study that recontacted a community sample of participants 48 hours after an interview about trauma and health topics. Seven percent reported an increase in being upset and 3% reported a decrease, but none reported regret about their participation (Newman, Walker, & Gefland, 1999).

Two epidemiological studies examined research participants' health care utilization after participation in a trauma-focused study. Interpreting this evidence is challenging because changes in service utilization from baseline postparticipation may indicate positive or negative outcomes. For example, increases in utilization may suggest that research facilitated treatment access or that it exacerbated symptoms. Studies thus far offer contradictory results. One study of PTSD in Australian combat veterans found that 6-month average health care utilization of services did not change after participation despite high rates of distress reported during the study interview (Parslow, Jorm, O'Toole, Marshall, & Grayson, 2000). The other study (Halek et al., 2005) involved American combat veterans. It found that few reported distress from survey participation and Veterans Affairs health care utilization subsequently decreased among the male participants in the 8 weeks after the survey. Among female veterans, however, a minority who served in combat, outpatient utilization increased. The authors speculate that this outcome may reflect trends in access to health care rather than reactions to the survey. Given the limited evidence, it remains good practice to routinely ask participants about emotional state at the end of a study session and to recontact those who report distress.

Unfortunately, we know little about the small subgroup for whom distress appears to increase during the postparticipation period. Demographic variables associated with participation-related distress include older age in adults, younger age in children, economic difficulties, a history of homelessness, being in prison, being single, and not having health insurance or a health care provider; psychological variables include lower self-efficacy, depression, neuroticism, self-destructiveness, aggression, and anxiety (Carlson et al., 2003; DePrince & Chu, 2008; Galea et al., 2005; Halek et al., 2005; Kassam-Adams & Newman, 2005; Ruzek & Zatzick, 2000; Walker, Newman, Kossm & Bernstein, 1997; Widom & Czaja, 2005). Some studies show women being more likely to report study-related distress (Black, Kresnos, Simon, Arias, & Shelley, 2006; Cromer et al., 2006; Dyregov, 2004; Galea et al., 2005; Widom & Czaja, 2005), whereas a smaller number do not (e.g., Ruzek & Zatzick, 2000). Similarly, income, minority status, education, and health status have been found to be correlates of distress in some studies, but not others (Halek et al., 2005; Johnson & Benight, 2003; Kassam-Adams & Newman, 2005; Ruzek & Zatzick, 2000; Widom & Czaja, 2005). It appears that many of these correlates are dependent on specific characteristics of the sampled group and the methodology.

Investigators have examined how extent of trauma exposure relates to participant distress in a variety of samples, but results vary in ways that may reflect differences across types of traumatic experiences and/or research methodologies. Extent of trauma exposure was not related to distress experienced during studies examining children, military veterans, community dwelling adults, expectant mothers, or acutely injured adults (Black et al., 2006; Chu et al., 2008; Parslow et al., 2000; Ruzek & Zatzick, 2000; Schwerdtfeger & Goff, 2008). However, extent of exposure was positively associated with distress for research samples comprised of participants who have a history of exposure to mass disaster, domestic violence, and other interpersonal trauma (Black et al., 2006; Boscarino et al., 2004; Galea et al., 2005; Johnson & Benight, 2003; Newman et al., 1999; Walker et al., 1997). Among college students, trauma history was unrelated to (Cromer et al., 2006, Sample 2, p. 350; DePrince & Freyd, 2004), positively correlated with (Cartier-Visscher, Naugle, Bell, & Suvak, 2007; Cromer et al., 2006, Sample 1, p. 350; Edwards et al., 2009), and negatively correlated with distress across studies (Newman et al., 2001).

Greater PTSD symptomatology is related to distress during trauma research in studies with veterans, women identified from a health maintenance organization, acutely injured adults, psychiatric inpatients, and survivors of interpersonal violence and mass disaster (Boscarino et al., 2004; Carlson et al., 2003; Galea et al., 2005; Johnson & Benight, 2003; Parslow et al., 2000; Ruzek & Zatzick, 2000; Walker et al., 1997; Widom & Czaja, 2005), but not in studies of children (Chu et al., 2008; Kassam-Adams & Newman, 2005). Studies of college students have been inconsistent with respect to the effects of PTSD status (Cromer et al., 2006; Edwards et al., 2009; Newman et al., 2001). Study-supplied referral for clinical services after participation may be an indicator of persistent research-related distress, but it also may reflect individuals using research participation as an incremental gateway into treatment (e.g., Halek et al., 2005). Published studies that report referral rates indicate that very few participants who are distressed at the end of a trauma-related protocol accept referrals or follow-up on the availability of a counselor (e.g., Galea et al., 2005). For example, only 11 of 5,001 (0.002%) participants in a survey about rape expressed interest in talking to a counselor the next business day after the interview (D. Kilpatrick, June 17, 2006, personal communication).

Finally, research involving individuals living in domestic abuse situations requires recognition of potential danger associated with study participation. Among 1,690 participants who reported exposure to interpersonal violence in a large survey, 1.4% endorsed an item asking whether answering questions about violence makes them feel afraid that someone might find out the answer and hurt them (Black et al., 2006). Although methods for promoting interpersonal safety for abuse victims have been described (Fontes, 2004; Sullivan & Cain, 2004), the effectiveness of such methods has not been evaluated in the context of research participation. It is worth noting that these threats are not unique to trauma-focused research, but may be of greater concern because of routine questioning about potentially traumatic experiences that implicate perpetrators.

In summary, a subgroup of participants experience emotional responses when engaging in trauma-related research, although it is unclear if these responses have enduring impact and qualify as research costs. Factors that increase the likelihood of emotional response to participation have been identified, but conclusions are limited. Finally, though much progress has been made in

examining emotional and physical costs of trauma-related research, future studies will require further conceptual and methodological clarity in conceptualizing emotional distress as a potential research risk and/or cost.

Benefit and Cost

Anticipated benefits of research should focus on both benefits to society and directly to participants (Levine, 1981, pp. 37–39), but trauma researchers tend to concentrate on participant benefits. A qualitative analysis of benefits reported by 100 research participants (Disch, 2001) identified a sense of helping others, along with personal benefits such as providing a helpful review of life events, increasing self-awareness, and reducing self-perceptions of blame. Similarly, Carlson and colleagues (2003) found that participants explained the usefulness of their experience in the study in terms of potentially aiding others, but also in terms of clarifying memories, generating feelings of relief, and facilitating recall of positive aspects of life. Studies using structured RRPQ items have found high endorsement levels for a general sense of benefit, personal meaningfulness of participation, positive self-esteem, and pride in helping others (Chu et al., 2008; Kassam-Adams & Newman, 2005; Newman et al., 2001; Newman et al., 1999; Ruzek & Zatzick, 2000; Widom & Czaja, 2005; Walker et al., 1999). Interestingly, financial considerations (i.e., payments to participants) are not widely cited as a relevant benefit in replies to open-ended queries following actual study participation.

Studies involving a range of child and adult trauma samples indicate that 46% to 88% of participants report benefiting from participation (Brabin & Berah, 1995; Kassam-Adams & Newman, 2005; Ruzek & Zatzick, 2000; Schwerdtfeger & Goff, 2008; Widom & Czaja, 2005). Perceived benefit commonly is related to overall positive appraisal of the research (e.g., DePrince & Chu, 2008; Martin, Perrott, Morris & Romans, 1999). In the few available studies, PTSD status has been found to be unrelated to (Carlson et al., 2003; DePrince & Chu, 2008: Johnson & Benight, 2003) or positively correlated with (Schwerdtfeger & Goff, 2008) self-reported benefit or usefulness of research participation.

The balance of cost and benefit has been examined in trauma-related research using such diverse indicators as (a) the percentage of participants who report both emotional distress and regret, (b) the difference between the RRPQ score for drawback (or negative emotions) and the score for personal benefit, and (c) willingness to participate in a similar study if invited again. Another method asks participants to consider their experience as a research subject and the importance of the research topic (Cromer et al., 2006). Some investigators have simply asked if the experience was positive, neutral, or negative (e.g., Martin et al., 1999).

Findings are broadly similar regardless of methodology. The majority of participants indicate that the benefits of their research participation outweigh the costs and/or that they would be willing to re-enroll if asked. Even within the small subset of participants who indicate marked or unexpected distress, the majority also endorse positive aspects of the experience (e.g., Brabin & Berah, 1995; Carlson et al., 2003; Kassam-Adams & Newman, 2005; Newman et al., 1999; Walker et al., 1997; Willebrand, 2008).

Trauma-focused studies that administer interviews have an equally or more favorable cost–benefit balance than questionnaire-based studies (DePrince & Chu, 2008; Newman et al., 1999; Walker et al., 1997). Interviews generally involve greater participant burden in terms of time and upset, but also appear to offer greater perceived benefit, an outcome that might be attributable to greater interpersonal interaction.

It is noteworthy that the aspects of studies that are most upsetting also are the ones most cited as benefits (e.g., remembering the past, recognizing memory gaps, experiencing painful insights and discussing the trauma; e.g., Carlson et al., 2003). Furthermore, evidence indicates that experiencing emotional distress does not translate to regret about participation (Draucker, 1999; Dyregov, 2004; Griffin et al., 2003; Johnson & Benight, 2003; Kassam-Adams & Newman, 2005; Newman et al., 1999; Ruzek & Zatzick, 2000; Walker et al., 1997). Overall, participants' own judgments about the balance between costs and benefits of participation appear to favor benefits, even for those who report experiencing distress (e.g., Dyregov, 2004; Johnson & Benight, 2003; Kassam-Adams & Newman, 2005; Ruzek & Zatzick, 2000).

SUMMARY AND FUTURE DIRECTIONS

There has been an encouraging proliferation of studies that address ethical dimensions of trauma-related research during the past 10 years. Researchers have taken the initiative to advance an evidence-based approach, prompted in part by the need to counteract seemingly overblown notions about the impact of trauma and the frailty of individuals with PTSD (Becker-Blease & Freyd, 2006). Increasingly there is systematic collection of information about rates of adverse reactions, operational measurement for risk and benefit, and evidence about ethical practices being included in study reports.

The bulk of evidence indicates that extraordinary precautions are not warranted for trauma-related studies in general. Individuals who have experienced trauma or developed PTSD do not appear to constitute a vulnerable group in terms of either susceptibility to coercion or impaired decision-making. Although distress may be experienced during participation in traumatic stress studies, the overall cost–benefit balance seems favorable. Even when participants endorse unexpected upset during a study, most signify willingness to repeat the experience or otherwise indicate no regret about participation. And, finally, trauma-related investigations that have asked participants to rate study procedures in terms of the minimal risk standard find that it applies well.

This largely reassuring body of evidence does not preclude the need for careful attention to ethical issues in research planning and execution. There is a minority for whom the overall

cost–benefit balance is not favorable and scientists need to understand more about this group. The aim is to identify these individuals in advance, to adequately warn them about potential emotional costs, and/or establish ways to alter the cost–benefit ratio for them.

There are still many unanswered questions. What level of detail about risks and benefits is best for participants during recruitment and informed consent for trauma-related studies? What combination of predictors indicates a participant at high susceptibility for regret and potential harm from study participation? How effective are the strategies that researchers use to mitigate distress or harm (e.g., warnings)? Finally, there are two important targets that would benefit from basic descriptive information (see Newman et al., 2006): How often do safety concerns and threats to confidentiality occur in trauma-related studies?

Simple steps such as greater consistency in collecting and reporting information bearing on ethical dimensions of research design will be valuable. For example, it would be helpful if all researchers routinely included information in publications about exclusion of participants due to impaired decision-making. Regular inclusion of descriptions of informed consent procedures and participants' ratings of risks and benefits could benefit future practice. Likewise, researchers might consider using common index terms for this area of study to facilitate sharing of information and ideas (i.e., participant reactions; research ethics). Methodologies are needed to define and assess minimal risk more carefully, perhaps using pre- and postassessments of distress as well as anchors linked to daily functioning. Finally, two challenging needs are for comparative studies to guide refinement of consent procedures and research that attempts to examine interacting factors associated with unfavorable cost–benefit ratios.

Nearly 30 years ago, Levine (1981) observed that, despite an underlying assumption about research participation being an unsafe endeavor, evidence indicated that "the role of research subject is not particularly hazardous" (p. 26). Contemporary evidence also indicates a general absence of harm and, in fact, a generally positive experience for most research participants including those who previously have been exposed to traumatic stress or developed PTSD. Continuing efforts to collect data relevant to the ethical dimensions of research will help refine our understanding of these considerations and improve both the human and scientific aspects of our studies.

REFERENCES

Becker-Blease, K., & Freyd, J. (2006). Research participants telling the truth about their lives: The ethics of asking and not asking about abuse. American Psychologist, 61, 218–226.

Black, M., Kresnow, M., Simon, T., Arias, I., & Shelley, G. (2006). Telephone survey respondents' reactions to questions regarding interpersonal violence. Violence and Victims, 21, 445–459.

Boscarino, J. A., Figley, C. R., Adams, R. E., Galea, S., Resnick, H., Fleischman, A. R., et al. (2004). Adverse reactions associated with studying persons recently exposed to mass urban disaster. Journal of Nervous and Mental Disease, 192, 515–524.

Brabin, P. J., & Berah, E. F. (1995). Dredging up past traumas: Harmful or helpful? Psychiatry, Psychology and Law, 2, 165–171.

Carlson, E., Newman, E., Daniels, J., Armstrong, J., Roth, D., & Loewenstein, R. (2003). Distress in response to and perceived usefulness of trauma research interviews. Journal of Trauma & Dissociation, 4, 131–142.

Carter-Visscher, R. M., Naugle, A. E., Bell, K. M., & Suvak, M. K. (2007). Ethics of asking trauma-related questions and exposing participants to arousal-inducing stimuli. Journal of Trauma and Dissociation, 8, 27–55.

Castor-Lewis, C. (1988). On doing research with adult incest survivors: Some initial thoughts and considerations. Women and Therapy, 7, 73–80.

Chu, A., DePrince, A., & Weinzierl, K. (2008). Children's perception of research participation: Examining trauma exposure and distress. Journal of Empirical Research on Human Research Ethics, 3, 49–51.

Collogan, L. K., Tuma, F., Dolan-Sewell, R., Borja, S., & Fleischman, A. R. (2004). Ethical issues pertaining to research in the aftermath of disaster. Journal of Traumatic Stress, 17, 352–363.

Cromer, L., Freyd, J., Binder, A., DePrince, A., & Becker-Blease, K. (2006). What's the risk in asking?: Participant reaction to trauma history questions compared with reaction to other personal questions. Ethics & Behavior, 16, 347–362.

DePrince, A., & Chu, A. (2008). Perceived benefits in trauma research: Examining methodological and individual difference factors in responses to research participation. Journal of Empirical Research on Human Research Ethics, 3, 35–47.

DePrince, A. P., & Freyd, J. J. (2006). The costs and benefits of being asked about trauma history. Journal of Trauma Practice, 3, 23–35.

Disch, E. (2001). Research as clinical practice: Creating a positive research experience for survivors of sexual abuse by professionals. Sociological Practice: A Journal of Clinical and Applied Sociology, 3, 221–239.

Draucker, C. B. (1999). The emotional impact of sexual violence research on participants. Archives of Psychiatric Nursing, 13, 161–169.

Dyregrov, K. (2004). Bereaved parents' experience of research participation. Social Science and Medicine, 58, 391–400.

Edwards, K. M., Kearns, M. C., Calhoun, K. S., & Gidycz, C. A. (2009). College women's reactions to sexual assault research participation: Is it distressing? Psychology of Women Quarterly, 33, 225–234.

Fontes, L. (2004). Ethics in violence against women research: The sensitive, the dangerous, and the overlooked. Ethics & Behavior, 14, 141–174.

Friedman, M. J. (2008). PTSD and vulnerability. Unpublished manuscript, National Center for Ethics in Health Care, Veterans Administration.

Galea, S., Nandi, A., Stuber, J., Gold, J., Acierno, R., Best, C., et al. (2005). Participant reactions to survey research in the general population after terrorist attacks. Journal of Traumatic Stress, 18, 461–465.

Griffin, M. G., Resick, P. A., Waldrop, A. E., & Mechanic, M. (2003). Participation in trauma research: Is there evidence of harm? Journal of Traumatic Stress, 16, 221–227.

Halek, K., Murdoch, M., & Fortier, L. (2005). Spontaneous reports of emotional upset and health care utilization among veterans with posttraumatic stress disorder after receiving a potentially upsetting survey. American Journal of Orthopsychiatry, 75, 142–15.

Hlavka, H., Kruttschnitt, C., & Carbone-López, K. (2007). Revictimizing the victims?: Interviewing women about interpersonal violence. Journal of Interpersonal Violence, 22, 894–920.

Johnson, L., & Benight, C. (2003). Effects of trauma-focused research on recent domestic violence survivors. Journal of Traumatic Stress, 16, 567–571.

Kassam-Adams, N., & Newman, E. (2002). The reactions to research participation questionnaires for children and for parents (RRPQ-C and RRPQ-P). General Hospital Psychiatry, 24, 336–342.

Kassam-Adams, N., & Newman, E. (2005). Child and parent reactions to participation in clinical research, General Hospital Psychiatry, 27, 29–35.

Kilpatrick, D. (2004). The ethics of disaster research: A special section. Journal of Traumatic Stress, 17, 361–362.

Leskin, L., & White, P. (2007). Attentional networks reveal executive function deficits in posttraumatic stress disorder. Neuropsychology, 21, 275–28.

Levine, C., Fadern, R., Grady, C., Hammerschmidt, D., Eckenwilder, L., & Sugarmen, J. (2004). The limitations of vulnerability as a protection for human research participants. American Journal of Bioethics, 43, 44–49.

Levine, R. J. (1981). Ethics and regulation of research. Baltimore, MD: Urban & Schwarzenberg.

Lidz, C. W., Appelbaum, P. S., Grisso, T., & Renaud, M. (2004). Therapeutic misconception and the appreciation of risks in clinical trials. Social Science & Medicine, 58, 1689–1697.

Martin, J. L., Perrott, K., Morris, E. M., & Romans, S. E. (1999). Participation in retrospective child sexual abuse research: Beneficial or harmful? What women think six years later. In L. M. Williams & V. L. Baynard (Eds.), Trauma and memory (pp. 149–160). Thousand Oaks, CA: Sage.

Matthieu, M., & Ivanoff, A. (2006). Treatment of human-caused trauma: Attrition in the adult outcomes research. Journal of Interpersonal Violence, 21, 1654–1664.

National Center for Ethics in Health Care. (2008). Should veterans with a diagnosis of post-traumatic stress disorder be considered a vulnerable population for the purpose of applying guidelines for the protection of human subjects in research? Washington, DC: Veterans Health Administration, National Center for Ethics in Health Care.

National Commission for the Protection of Human Subjects of Behavioral Research. (1979). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (DHEW Publication No. OS 78-0012). Washington, DC: Department of Health, Education, and Welfare.

Newman, E., & Kaloupek, D. (2004). The risks and benefits of participating in trauma-focused research studies. Journal of Traumatic Stress, 17, 383–394.

Newman, E., Risch, E., & Kassam-Adams, N. (2006). Ethical issues in trauma-related research: A review. Journal of Empirical Research on Human Research Ethics, 1, 29–46.

Newman, E., Walker, E. A., & Gefland, A. (1999). Assessing the ethical costs and benefits of trauma-focused research. General Hospital Psychiatry, 21, 1–10.

Newman, E., Willard, T., Sinclair, R., & Kaloupek, D. (2001). The costs and benefits of research from the participants' view: The path to empirically informed research practice. Accountability in Research, 8, 27–47.

Parslow, R. A., Jorm, A. F., O'Toole, B. I., Marshall, R. P., & Grayson, D. A. (2000). Distress experienced by participants during an epidemiological survey of posttraumatic stress disorder. Journal of Traumatic Stress, 13, 465–471.

Qureshi, K. A., Gerson, R. R. M., Smailes, E. S., Raveis, V. H., Murphy, B., Matzner, G., et al. (2007). Roadmap for the protection of disaster research participants: Findings from the World Trade Center evacuation study. Prehospital and Disaster Medicine, 22, 486–493.

Rosenstein, D. (2004). Decision-making capacity and disaster research. Journal of Traumatic Stress, 17, 373–381.

Ruzek, J., & Zatzick, D. (2000). Ethical considerations in research participation among acutely injured trauma survivors: An empirical investigation. General Hospital Psychiatry, 22, 27–36.

Schwerdtfeger, K., & Goff, B. S. N. (2008). The effects of trauma-focused research on pregnant female participants. Journal of Empirical Research on Human Research Ethics, 3, 59–67.

Sullivan, C., & Cain, D. (2004). Ethical and safety considerations when obtaining information from or about battered women for research purposes. Journal of Interpersonal Violence, 19, 603–618.

U.S. Department of Health and Human Services. (2005). Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.102i. Retrieved September 14, 2009, from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

Walker, E. A., Newman, E., Koss, M., & Bernstein, D. (1997). Does the study of victimization revictimize research participants? General Hospital Psychiatry, 19, 403–410.

Weitlauf, J., Ruzek, J., Westrup, D., Lee, T., & Keller, J. (2007). Empirically assessing participant perceptions of the research experience in a randomized clinical trial: The Women's Self-Defense Project as a case example. Journal of Empirical Research on Human Research Ethics, 2, 11–24.

Widom, C. S. (1989). The cycle of violence. Science, 244, 160–166.

Widom, C. S., & Czaja, S. J. (2005). Reactions to research participation in vulnerable subgroups. Accountability in Research, 12, 115–138.

Willebrand, M. (2008). Presence of psychiatric morbidity and regrets about participation in trauma-related research—a pilot study. General Hospital Psychiatry, 30, 476–478.